United States
Environmental Protection
Agency

Office of Prevention,
Pesticides
and Toxic Substances
(7501C)

PESTICIDE FACT SHEET

Name of Chemical(s): Polyoxin D Zinc Salt

Reason for Issuance: Registration

Date Issued: August, 1997

Fact Sheet Number:

1. DESCRIPTION OF THE CHEMICAL

Generic Name(s) of the Active Ingredient(s):	Polyoxin D Zinc Salt, zinc 5-[[2-amino-5-O-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate
OPP Chemical Codes	230000
Year of Initial Registration:	1997
Pesticide Type:	Biochemical-like fungicide
U.S. and Foreign Producers:	Kaken Pharmaceutical Co., Ltd.

2. USE SITES, APPLICATION TIMING & TARGET PESTS

The proposed end-use involves foliar spray applications of wettable powder to turf sites including golf courses, home lawns, parks and commercial and institutional grounds to control *Rhizoctonia solani*, the causative agent of Brown Patch and Large Patch disease. It is not for use on turf being grown 1) for sale or other commercial use as sod, 2) for commercial seed production, or 3) for research purposes. Application of the end-use product is to be made on a 7 - 14 day schedule, as necessary.

3. SCIENCE FINDINGS

A. TOXICOLOGY:

All toxicology data requirements have been satisfied for the purpose of

the unconditional registration. The information submitted to support the acute toxicity requirements for polyoxin D zinc salt indicate Toxicity Category III for acute dermal toxicity and primary eye irritation, and Toxicity Category IV for acute oral toxicity, acute inhalation toxicity, and primary dermal irritation. Polyoxin D zinc salt is a mild sensitizer. However, due to the test method (guinea pig maximization test) and the absence of reported hypersensitivity incidents, dermal sensitization precautionary text is not required to appear on the manufacturing product label.

B. HUMAN HEALTH EFFECTS:

No unreasonable adverse effects to human health are expected from the use of polyoxin D zinc salt.

1. Risks Posed by Potential Dietary Exposure

There are no food uses associated with the registration of polyoxin D zinc salt. Therefore, acute and chronic dietary risks should be minimal based on lack of exposure. Furthermore, results from mammalian acute and chronic toxicity studies indicate lack of toxicity, adding further weight to the lack of risk from exposure to polyoxin D zinc salt.

2. Effects on Immune and Endocrine Systems

The Agency is not requiring information on the endocrine effects of this biochemical pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects. However, BPPD has considered, among other relevant factors, available information concerning whether the biochemical-like compound may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. The active ingredient, polyoxin D zinc salt, acts as a fungal chitin synthetase inhibitor. There is no known evidence so far that this compound acts as an endocrine disrupter in humans. Available developmental toxicity data do not indicate that polyoxin D zinc salt has any endocrine effects. Furthermore, results from chronic exposure and oncogenicity studies showed no significant toxic or oncogenic responses from polyoxin D zinc salt. Therefore, no adverse effects to the endocrine or immune systems are known or expected.

3. Risks Posed by Potential Residential, School or Daycare Exposure

No indoor residential, school or daycare uses currently appear on the label. The proposed use pattern is for turf sites only. Non-dietary exposure at these sites could occur where children are present, but the health risk is expected to be minimal to nonexistent based on evaluations of the submitted studies and the low toxicity of polyoxin D zinc salt.

4. Potential for the Transfer of the Pesticide to Drinking Water

Although the potential exists for a minimal amount of polyoxin D zinc salt to enter the ground water or other drinking water sources if, after application, weather patterns are such that significant rainfall and surface water runoff occur, the health risk to humans is considered negligible based on the evaluations of the submitted toxicity studies, and the low application rate of the active ingredient.

5. Acute and Chronic Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

There are no food uses associated with the registration of polyoxin D zinc salt. Therefore, acute and chronic dietary risks should be minimal based on lack of exposure. Furthermore, results from mammalian acute and chronic toxicity studies indicate lack of toxicity, adding further weight to the lack of risk from exposure to polyoxin D zinc salt.

It is feasable that infants and children could incur minimal dietary exposure if, when they come into contact with recently treated turf, they either ingest treated turf foliage or transfer residues from turf to hand to mouth. However, the Agency has no information to indicate that children or infants would be more sensitive than adults to effects caused by polyoxin D zinc salt. Therefore, based on the lack of chronic and acute toxicity in the submitted studies, the potential risks to infants and children are considered negligible.

6. Aggregate Exposure From Multiple Routes Including Dermal, Oral, and Inhalation

Aggregate exposure would primarily occur in the mixer/loader/applicator subpopulation, via dermal and inhalation routes. Risks associated with dermal and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the pulmonary studies for both the technical and end-use product showed no adverse effects (both Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal studies using the technical and using the end-use product indicated low toxicity (Toxicity Category III), and no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible.

C. ECOLOGICAL EFFECTS:

Data waivers were granted for non-target plants and honeybee toxicity

studies based on the limited turf only application sites and expected minimal exposure to pollinating insects, i.e. honeybees.

Ecological effects studies were performed on mallard duck, freshwater invertebrates, rainbow trout, and non-target insects including two-spotted spider mites, brown plant hoppers, and diamond back moths. Toxicological studies indicated that there is no significant toxicity to rodents from acute oral testing at the maximum hazard dose. Therefore, risk to mammalian wildlife is expected to be minimal to nonexistent. Polyoxin D zinc salt was found to be practically non-toxic to the mallard duck, which is a representative species for avian risk assessment. Based on the results of the non-target insect study, exposure to polyoxin D zinc salt is not expected to pose significant increased risks to terrestrial insects. In the studies submitted, moderate toxicity to aquatic species (freshwater invertebrates and rainbow trout) was observed. No unreasonable adverse ecological or environmental fate effects were identified by the duck, mite and insect testing. Potential exposure to freshwater invertebrates and fish will be minimized by appropriate precautionary labeling.

4. SUMMARY OF DATA GAPS

There are no data gaps. There exists a potential risk to aquatic species. However, exposure to aquatic species is considered minimal to negligible when the end-use product containing the active ingredient is used according to label instructions.

5. REGULATORY ACTIONS

The first, unconditional, registrations were issued in August of 1997.

6. CONTACT PERSON AT EPA

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